510(k) SUMMARY

CLARIANCE's Idys™ LIF Cages

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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OCT 10 2013

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Date Prepared: October 9, 2013

Name of Device and Name/Address of Sponsor

CLARIANCE - Idys™ LIF Cages

Common or Usual Name

Lumbar Intervertebral Body Fusion Device

Classification Name

21 C.F.R. 888.3080 - Intervertebral body fusion device

Product Code

MAX

Predicate Devices

Eisertech, LLC's PLIF Cage

K2M, Inc.'s Aleutian IBF System

Synthes Spine's OPAL Spacer

Intended Use / Indications for Use

The Idys™ LIF Cages are indicated for use with autologous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation which has been cleared by FDA for use in the lumbar spine.

Device Description

The Idys™ LIF Cages consist of PEEK lumbar cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The Idys™ LIF Cages also feature markers made of Tantalum according to ASTM F560.

The Idys™ LIF Cages have different anatomic shapes and dimensions based on the surgical approach: PLIF (posterior lumbar interbody fusion); TLIF (transforaminal lumbar interbody fusion); and PTLIF (posterior approach and oblique-TLIF approach).

The Idys™ PLIF Cage is a hollow spacer with openings for autograft on the top, bottom, and sides of the device.

the Idys™ TLIF Cage has a bullet tip to facilitate introduction. The TLIF Cage Holder instrument has a clamp that affixes to the axle to enable rotation of the device during its introduction *in situ*.

The Idys™ PTLIF Cage is inserted in an oblique position. It can be introduced with a PLIF approach or a TLIF approach to the convenience of the surgeon and with taking into account the profile of the patient.

The Idys™ LIF Cage procedures are performed using a set of surgical instruments common for PLIF and TLIF approaches. Most of the instruments provided are common surgical tools used in these types of interbody fusion procedures. Those instruments are considered Class I, general purpose, manual orthopedic instruments encompassed within the regulation in 21 CFR 888.4540.

Comparison of Technical Characteristics

	CLARIANCE's Idys™ LIF Cages	**Eisertech, LLC's PLIF Cage (K113478)**	**K2M, Inc.'s Aleutian IBF System (K082698)**	**Synthes Spine's Synthes OPAL Spacer (K072791)**
Anatomical sites	L2 to S1	L2 to S1	L2 to S1	L2 to S1
Material	INVIBIO PEEK OPTIMA LT1	INVIBIO PEEK OPTIMA or Zeniva PEEK	INVIBIO PEEK OPTIMA LT1	PEEK
Radiographic Marker Components	Tantalum markers; ASTM F136 Titanium alloy cage axle (TLIF Cage only)	Commercially pure titanium markers grade 2, per ASTM F67	Tantalum markers	N/A
Surgical Approaches	PLIF, TLIF, PTLIF	PLIF	PLIF, TLIF, PTLIF	PTLIF
PLIF Dimensions	Length: 20, 25 mm Height: 8-14 mm Width: 11 mm	Length: 20-30 mm Height: 7-16 mm Width:8-12 mm	Length: 22, 26 mm Height: 7-17 mm Width: 10 mm	N/A
TLIF Dimensions	Length: 29 mm Height: 7-14 mm Width: 11 mm	N/A	Length: 27 mm Height: 7-17 mm Width: 10 mm	N/A
PTLIF Dimensions	Length: 28, 32 mm Height: 8-14 mm Width: 11 mm	N/A	Length: 28, 32, 36 mm Height: 7-15 mm Width: 10, 12 mm	Length: 28, 32 mm Height: 7-17 mm Width: 10 mm

Performance Data

Performance testing was conducted per ASTM F2077 and ASTM F2267. Specifically, CLARIANCE performed static and dynamic axial compression testing, static and dynamic compression shear testing, subsidence testing, expulsion testing, torsion testing, and wear testing. The results of these studies were determined to be substantially equivalent to legally marketed devices.

Substantial Equivalence

The Idys™ LIF Cages are substantially equivalent to Eisertech, LLC's PLIF Cage (K113478), K2M, Inc.'s Aleutian IBF System (K082698), and Synthes Spine's OPAL Spacer (K072791). The Idys™ LIF Cages have the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the Idys™ LIF Cages and its predicate devices raise no new issues. Performance data demonstrate that the Idys™ LIF Cages are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

CLARIANCE
% Janice M. Hogan, Esq.
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K131178
Trade/Device Name: Idys™ LIF Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 30, 2013
Received: August 30, 2013

Dear Esquire Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

for

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131178

Device Name: Idys™ LIF Cages

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices